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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,110	11/18/2005	Jerome Siegel	2307AA-128410US	2706

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,110	SIEGEL ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,27,29 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,27,29,37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 15 October 2008 have been entered. Claims 1 - 17, 27, 29, and 37 are pending and under examination.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 October 2008 has been entered.

Withdrawn Rejections

3. The following rejections set forth in the previous office action are withdrawn:

A. The rejections of claim 37 as anticipated by Kiyashchenko (paragraph 4 of the office action mailed 26 August 2008), Haynes (paragraph 5), Siegel 7,112,566 (paragraph 6), Siegel 7,335,640 (paragraph 7), and Taheri (paragraph 8) are withdrawn in light of the amendments. Claim 37 now explicitly requires that the hyporcretin be administered to a patient who is overweight or suffering from a weight disorder or obesity. None of these references explicitly teach administering the drug to these patient populations.

B. The obviousness-type double patenting rejections over U.S. Patent 7,112,566, 7,335,640, and application 11/937891 are withdrawn in light of the amendments to the claims. The present claims now require that the patients have weight disorders or are overweight or obese; the claims in the other cases do not require this limitation.

C. The concerns about inventorship (paragraph 14 of the office action mailed 26 August 2008) are moot. The present claims no longer conflict with those of the other applications. Additionally, applicant's representative has unequivocally stated that at the time the present invention was made, it was owned by or subject to obligation of assignment to the same entity (remarks filed 15 October 2008, page 7).

Claim Objections

4. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 recites "the hypocretin or agonist thereof", but it depends from claim 1 which does not allow for the use of agonists. Therefore claim 1 broadens, rather than narrows, claim 15.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 - 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering hypocretins and subsequently increasing gross motor activity, does not reasonably provide enablement for reducing excessive weight or preventing the development of further excess body weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection stands for the reasons set forth in the previous office actions. Briefly, hypocretin-1 and hypocretin-2 (also known as orexin-A and -B respectively, see paragraph [46] of the specification) are known in the art to increase feeding behavior. The specification shows an example wherein administration of hypocretin-1 results in short-term (60 minutes) increase in locomotor activity (Figure 1 and paragraph [11] for example) but fails to show decrease of weight as recited in claim 2, or prevention of further increase in weight as recited in claim 3. There is no reduction to practice or working example of the methods of claims 2 - 3. In fact, given that the hypocretins are known to increase feeding, it is more likely than not that administration of them will result in increase in body weight, not decrease or prevention of further increase as claimed. Given that the specification provides no working examples of weight loss or prevention of weight gain upon administration of the hypocretins, and the art recognizes that phenomena consistent with the opposite effect (namely stimulating of feeding) would

occur, and the specification offers no guidance as to how to overcome the art-recognized obstacles, it would take undue experimentation in order to practice the full scope of claims 2 - 3.

Applicant argues that the amendments are sufficient to overcome the rejection under 35 USC 112, first paragraph, as weight loss and prevention of weight gain have been deleted from the independent claims. While true, the dependent claims subject to this rejection still are drawn to that subject matter. Therefore, the rejection of these claims stands.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 6 - 17, 27, and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Stricker-Krongrad 2002 (Regulatory Peptides 104:11-20, published online 11 December 2001, of record).

Stricker-Krongrad teaches administration of hypocretin-1 and hypocretin-2 to obese mice. See p. 12 first complete paragraph for identification of obese mice and p. 14 section 2.4.2 for explanation of administration of the peptides. Applicant argues, on p. 7 of the remarks filed 15 October 2008, that while the reference teaches that the dose of hypocretin administered increases feeding, this does not necessarily mean that locomotion was increased. According to applicant, since all claims now require that the amount administered is effective to increase locomotion or gross motor activity, the reference cannot anticipate the claims.

Applicant's arguments have been fully considered but they are not persuasive. Stricker-Krongrad teaches administering as much as 10 nmol of hypocretin to obese mice. See p. 14 first complete paragraph for the dose, p. 12 first complete paragraph for indication that the mice were obese as required by independent claims 1, 17, 27, and 37. As hypocretin-1 has a molecular mass of 3562 Daltons (specification, paragraph [46]), this means that 35.62 ng of the protein was administered. Since mice weigh 30 grams on average, 35.62 ng were administered to 0.03 kg animals, which is a dose of 1187

ng/kg, or 1.187 μg/kg. The specification explicitly states (paragraph [115]) that anywhere from 0.05 μg/kg to 10 μg/kg is an effective dose. Since the prior art reference teaches administering an effective dose of the peptide to obese animals, the effects recited in the claims (e.g. "sufficient to increase gross motor activity in the individual" as recited in claim 1 and "results in the increased locomotion" recited in claim 27) are necessarily provided for. Therefore, claims 1, 17, 27, and 37 are anticipated. Note that the obese mice suffer from behavioral symptoms of weight disorders, including inactivity as recited in claim 37.

Claim 6 is anticipated as intracerebroventricular injections were performed by Stricker-Krongrad. Claims 7 and 10 are anticipated as the mice are obese. Claims 8 - 9 are anticipated as the obese mice suffer from decreased levels of hypocretin at the mRNA and protein levels (see for example abstract of Stricker-Krongrad). Claim 11 is anticipated as the obesity is determined by body weight. Claim 12 is included in this rejection; although the reference does not explicitly report the BMI of the mice, it is reasonable that they have the recited property (BMI > 30) as they are obese; inclusion of this claim in the rejection is proper as the limitation is a property that appears to be inherent (see MPEP § 2112). Claim 13 is anticipated as the mice are overweight. Claim 14 is anticipated as it recites an effect which will necessarily occur upon administration; note that i.c.v. injection of hypocretins increases metabolic rate (p. 17 first complete paragraph). Claim 15 is anticipated as the hypocretin is administered in a pharmaceutical composition with vehicle (see Figure 5 and paragraph spanning pp. 13 - 14). Claim 16 is anticipated as the animals are free of narcolepsy.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were

made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4 - 17, 27, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stricker-Krongrad 2002 in view of Haynes 1999 (Peptides 20:1099-1105, of record).

The reasons why claims 1, 6 - 17, 27, and 37 are anticipated by Stricker-Krongrad are set forth above. Briefly the reference teaches administering hypocretins and monitoring certain physiological parameters. However Stricker-Krongrad does not teach monitoring signs of the excess body weight as recited in claim 4 or monitoring body weight as recited in claim 5.

Haynes teaches that administering hypocretins (also known as orexins) results in increased body weight, and teaches monitoring body weight after the injections (see for example Table 1 on p. 1103). This is on point to claims 4 and 5. However Haynes does not teach administration to obese animals as encompassed by claim 1.

It would have been obvious to one of ordinary skill in the art to modify the methods of Stricker-Krongrad to include the step of monitoring body weight as taught by Haynes, thereby arriving at the invention of claims 4 - 5. The motivation to do so would be to confirm the effect of the hypocretin.

8. Claims 1, 6 - 17, 27, 29 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stricker-Krongrad 2002 in view of Ida 199 (Brain Research 821:526-529, reference AE on IDS filed 6 June 2005).

The reasons why claims 1, 6 - 17, 27, and 37 are anticipated by Stricker-Krongrad are set forth above. Briefly the reference teaches administering hypocretins and monitoring certain physiological parameters. However Stricker-Krongrad does not teach monitoring locomotion after the administration, as recited in claim 29.

Ida teaches that administering orexin-A and -B, which are synonymous with hypocretin-1 and -2, increases burrowing in rats; see Figure 2B. Ida also teaches that orexin-B increases searching behavior (Figure 3A). As searching and burrowing are

both specific types of behaviors that require locomotion, these are on point to claim 29. However while Ida teaches administration to rats, the reference does not explicitly teach administration to obese animals as encompassed by claim 27.

It would have been obvious to one of ordinary skill in the art to modify the methods of Stricker-Krongrad to include the step of monitoring locomotion (i.e., either burrowing or searching) as taught by Ida, thereby arriving at the invention of claim 29. The motivation to do so would be to confirm the effect of the hypocretin.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
February 18, 2009